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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/767,296 | 01/28/2004 | John Y. Yan | 50623.360 | 5005 |
| <div>7590 06/09/2009</div> <div>Paul J. Meyer, Jr. Squire, Sanders & Dempsey L.L.P. 1 Maritime Plaza, Suite 300 San Francisco, CA 94111</div> | | | | |
| EXAMINER | | | | |
| WOO, JILLAN W | | | | |
| ART UNIT | | PAPER NUMBER | | |
| 3773 | | | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/767,296

Applicant(s)

YAN, JOHN Y.

Examiner

Julian W. Woo

Art Unit

3773

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/7/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28, 44, 45, 50, 52 and 54-61 is/are pending in the application.
- 4a) Of the above claim(s) 55-57 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28, 44, 45, 50, 52, 54 and 58-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 4/7/09
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 31, 2009 has been entered.

Election/Restrictions

2. Newly submitted claims 55-57 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The stent of the newly-submitted claims includes, inter alia, a strut element including a network of attached particles forming a porous metallic core, which is distinct from the strut element including a solid metallic core found in the originally-claimed invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 55-57 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

3. Claims 59 and 60 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not describe a metallic sheet devoid of polymeric material.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
 2. Ascertaining the differences between the prior art and the claims at issue.
 3. Resolving the level of ordinary skill in the pertinent art.
 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 28, 44, 45, 50, 52, 54, and 58-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (5,015,253 or '253) in view of MacGregor (4,355,426 or '426), and further in view of Khosravi et al. (5,441,515). MacGregor '253 discloses the invention substantially as claimed. Macgregor '253 discloses, at least in the figures and in col. 4, lines 7-17 and col. 5, lines 51-60; a stent comprising a strut element including a solid metallic inner core having opposed inner and outer sides (i.e., a luminal side and an exterior, tissue-facing side, respectively) and an outer layer

disposed on the outer side and an inner layer disposed on the inner side, where the outer layer is made from a first porous material formed by particles sintered to the inner core; where the inner layer is made from a porous material the inner layer being a second porous layer of material formed by particles sintered to the inner core, and where the stent is configured for being radially expanded by a balloon and for providing support to a body vessel. However, MacGregor '253 does not disclose that the first and second layers are of metallic material, where the layers are configured to contain therapeutic agents as claimed. MacGregor '426 teaches, at least in col. 3, lines 18-56 and col. 8, line 39 to col. 10, line 51; a cardiovascular device including a metallic core including a layer of metallic material sintered the metallic core. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of MacGregor '426, to apply a metallic material in the layers of the stent of MacGregor '253. A metallic material would allow a stent to have biocompatible, porous layers with excellent wear and strength characteristics.

However, neither of the MacGregor references, alone or in combination, discloses that a strut element of the stent or the entire stent comprises a metallic sheet or a metallic sheet having opposed ends, forming a cylinder, and devoid of a polymeric material. The MacGregor references also do not disclose that the stent includes one or more therapeutic agents impregnated within the porous metallic layers and releasable at an implant site, and that the stent is coiled and includes a head portion, at least two slots and tail portions receivable in the slots. Khosravi et al. teach, at least in figure 21 and col. 7, lines 21-38; col. 8, line 65 to col. 9, line 7; and col. 10, line 56-58; a stent

including a metallic sheet or a metallic sheet having opposed ends, forming a coiled cylinder, and devoid of a polymeric material, a head portion, at least two slots (e.g., unlabeled, serrated slots) and tail portions (at the top edge of the sheet as seen in fig. 21) receivable in the slots. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Khosravi et al., to modify the stent of MacGregor '253 in view of MacGregor '426, so that the stent or its strut element comprises a metallic sheet, a head portion, at least two slots and tail portions receivable in the slots. Such modifications would allow the stent to be inserted into a body lumen, to be expanded, and to be reliably locked in an enlarged diameter form for maintaining the patency of the body lumen. Khosravi et al. further teach one or more therapeutic agents impregnated within the surfaces of their stent, where the agents are releasable at an implant site. It would also be obvious to one having ordinary skill in the art at the time the invention was made, in view of Khosravi et al., to include one or more therapeutic agents in the porous metallic layers of the stent of MacGregor '253 in view of MacGregor '426. Such a modification would prevent blood coagulation or hyperplastic response from a blood vessel, or reduce the likelihood of restenosis at the implant site.

Response to Amendment

6. Applicant's arguments with respect to claims 28, 44, 45, 50, 52, 54, and 58-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kropf (4,760,849) teach a coiled stent formed from a metallic sheet.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Julian W. Woo/
Primary Examiner, Art Unit 3773